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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/516,616

06/10/2005

Ilan Ziv

26549U

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08/07/2007

NATH & ASSOCIATES
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Alexandria, VA 22314

EXAMINER

JONES, DAMERON LEVEST

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

08/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/516,616

Applicant(s)

ZIV ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 84-98 and 100-108 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 84, 97, 100-103, and 109 is/are rejected.
- 7) ☒ Claim(s) 85-96, 98, 104-108 and 110 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of Applicant's amendment filed 5/21/07 wherein claims 1-83 and 99 were canceled; claims 84-98, 101, 102, 105, 107, and 108 were amended; and claim 110 was added.

Note: Claims 84-98 and 100-108 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments and/or amendment filed 5/21/07 to the rejection of the claims made by the Examiner under 35 USC 112, first and second paragraphs, have been fully considered and deemed persuasive-in-part for the reasons set forth below.

112 First Paragraph Rejection

The rejection of claims 100-103 and 109 under 35 USC 112, first paragraph, as failing to comply with the enablement requirement is MAINTAINED for reasons on record in the office action mailed 2/21/07 and those set forth below.

Applicant asserts that the subject matter is directed to detection, not treatment, of a well defined, phenomenon manifested in a defined group of physiological disorders. Applicant asserts that the phenomenon is the perturbation of the normal organization of the cell plasma membrane. In addition, Applicant asserts that the claims describe a method for detecting the intrinsic cellular mechanism manifested in physiological disorders characterized by the occurrence of perturbed membrane cells. Hence, Applicant concludes that the method can readily be performed without undue experimentation.

Applicant's arguments have been considered, but are not found persuasive. It is duly noted that the claims are directed to a method of detecting physiological disorders. The various possible physiological disorders encompassed by the instant invention are not limited to a well defined group of disorders. In the specification (page 2, lines 8-12), for example, it is disclosed that perturbations and alterations of the cell plasma membrane occur in numerous physiological and pathological conditions and are characterized by a plurality of diseases. Thus, the breadth of the claims is such that they read on the detection of any physiological disorder associated with a perturbed membrane. The quantity of experimentation needed is undue. One of skill in the art would need to determine what physiological disorder(s)/disease(s) out of all the conditions known to exist would be detectable using the method of the instant invention. Also, it should be noted that the level of skill in the art is high due to the unpredictability in the pharmaceutical art. As a result, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and/or in vivo screening to determine if the desired result as set forth in the instant invention is obtained. Thus, it is unclear which diseases/disorders would be compatible with the instant invention. Furthermore, the various possible conditions/diseases/disorders involve a multitude of cellular mechanisms. Hence, there is no absolute predictability of whether the instant invention is capable of detecting a multitude of conditions/disorders/diseases. The existence of such obstacles establishes that the knowledge in the art would prevent one of ordinary skill in the art from accepting that all possible physiological conditions are detectable using the instant invention. Once

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again, it is noted that the assumption that all physiological disorders are detectable using the instant invention is an incredible finding for which Applicant have not provided supporting evidence. Thus, the restriction is deemed proper and is MAINTAINED.

112 Second Paragraph Rejection

I. The 112, second paragraph, rejections over claims 84, 96, 99, and 108 are WITHDRAWN because Applicant has amended or canceled the claim to overcome the rejection.

II. The rejection of claim 97 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is MAINTAINED for reasons of record in the office action mailed 2/21/07 and those set forth below.

Applicant asserts that since the claim has been amended to delete the recitation of an active compound, the rejection is overcome.

The rejection is being maintained on the basis that one still cannot ascertain the properties that Applicant is referring to which are detectable. The issue here is not whether the compound is active or not, but what Applicant intends by the phrase 'having detectable properties of its own'. What properties is Applicant referring to?

II. The rejection of claims 100 and 109 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is MAINTAINED for reasons of record in the office action mailed 2/21/07 and those set forth below.

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Applicant asserts that the claims are not indefinite because claim 100 clearly describes that the physiological disorders are those characterized by the presence of cells having perturbed membranes and some of the disorders are listed in the claim at pages 13-14 and 16-17.

Applicant's arguments are not found persuasive because the claims are given their broadest reasonable interpretation. As a result, the claims are not limited to the disorders listed in the specification. The claims read on any and all physiological disorders that have a perturbed membrane. As a result, one cannot ascertain what specific disorders the claims read upon since there are a multitude of disorders known to man. Thus, the claims are indefinite and the rejection is deemed proper.

NEW GROUNDS OF REJECTION

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 84 is rejected under 35 U.S.C. 102(b) as being anticipated by Wilkinson (Journal of Chromatographic Science, 1978, Vol. 16, No. 11, pages 547-552).

Wilkinson discloses a compound N2,N6-bis[[5-(dimethylamino)-1-naphthalenyl]sulfonyl]-lysine (also known as bis-Dns-Aec, page 550, Table I) that encompasses Applicant's Formula II. Thus, both Wilkinson and Applicant disclose overlapping species when both R groups is CH₃; both G groups on the N-G group are

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hydrogen; one G group attached to the C-M group is COOH (M is hydrogen) and the other G is hydrogen (M is hydrogen); both V are $(CH_2)_k$ where $k = 1$; and T is sulfur.

Note: It should be noted that **bis-Dns-Aec** is the shorthand for **Dns (also known as dansyl)** which is 1-dimethylamino-naphthylene-5-sulphonyl; **bis** which is the prefix meaning 'twice' or 'again' that is used in chemical nomenclature to indicate that a chemical grouping or radical occurs twice in a molecule; and **Aec** which is S-beta-aminoethylcysteine.

CLAIM OBJECTIONS

5. Claims 85-96, 98, 104-108, and 110 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Note: The claims are distinct over the instant invention because of the additional limitations in the dependent claims.

COMMENTS/NOTES

6. The Examiner respectfully suggests that Applicant make the following changes in order to clarify the instant invention. (1) In claim 84, line 8, replace 'among' with 'from'; (2) claim 1, line 9, replace 'is selected from the group consisting of' with 'contains'; (3) claim 1, line 11, replace 'V groups...or $-(CH_2)_k$ ' with 'V groups are independently absent or $-(CH_2)_k$ '; (4) claim 1, lines 13-14, replace 'M groups are...fluoroalkyl' with 'M groups are independently absent or selected from the group consisting of


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hydrogen...fluoroalkyl'; (5) claim 1, line 21, insert 'or' before 'a marker for PET scan; (6) claim 1, line 23, insert 'independently selected from the group consisting of' before 'hydrogen'; and (6) claim 1, lines 24-25, delete ',R moieties are either the same or different'.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


D. L. Jones
Primary Examiner
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August 1, 2007